IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	William P. Spencer, et al.
Appl. No.	:	10/805,386
Filed	:	March 22, 2004
Title	:	ESTERIFIED FATTY ACID COMPOSITION
Examiner	:	D. Carr
Group Art Unit	:	1621
Conf. No.	:	1731

SECOND DECLARATION OF THOMAS VAN DYKE
SUBMITTED UNDER 37 C.F.R. § 1.132

I, Thomas Van Dyke, DDS, declare as follows:

1. I am a professor at the Department of Periodontology and Oral Biology, Boston University Goldman School of Dental Medicine. I also serve as a scientific advisor for Imagenetix, Inc., the assignee of the above-captioned patent application.

2. I received my D.D.S. (1973) from Case Western Reserve University; M.S. (1979) from State University of New York (SUNY) at Buffalo in Oral Sciences and my Ph.D. (1982) from SUNY at Buffalo in Oral Biology. I received the International Association for Dental Research (IADR) Award for Basic Research in Periodontology in 2001 and the Norton Ross Award for Excellence in Clinical Research in 2002. I serve or have served on the editorial boards of Infection and Immunity (1989-present); Journal of Periodontology (1988-present), Journal of Periodontal Research (1987-present); Journal of Clinical Periodontology (1991-1995), Journal of Public Health Dentistry (1991-1995), Current Opinions in Periodontology (1993). I served as President of the Periodontal Diseases Research Group of the IADR from 1991-1992. I have authored/co- authored over 200 original articles, and numerous abstracts and book chapters. I am a member of the American/International Association of Dental Research, American Academy of Periodontology, American Dental Association, and a Diplomate of the American Board of Periodontology. My research interests are the structural and functional relationship of abnormalities of the inflammatory process with focus on regulation of phagocytic cells, in the etiology and pathogenesis of periodontal diseases. I am well-known in the scientific community for my work on the pathways of resolution of inflammation and pathogenesis of periodontal diseases, neutrophil biology, and clinical research.

3. I have read and understood the specification of the above-captioned patent application, the currently pending claims as submitted to the U.S. Patent and Trademark Office (PTO) on January 8, 2008, and the most recent Office Action, mailed by the PTO on April 4, 2008.

4. The currently pending claims are directed to a method of treating periodontal disease by administering a cetylated fatty acid, chosen from among cetylated decanoic acid, cetylated lauric acid, cetylated myristic acid, cetylated palmitoleic acid, cetylated oleic acid, and cetylated stearic acid, to a patient. The cetylated fatty acid is thought to have anti-inflammatory effects that aid in the treatment of periodontal disease.

5. As I have already declared in a previous declaration filed in the present application on January 8, 2008 (Van Dyke First Declaration), it has been known for some time that the administration of anti-inflammatory drugs can aid in the treatment of periodontal disease.

6. Treatment of periodontal disease requires administration of anti-inflammatory drugs to the patient for an extended period of time. The prolonged administration exposes the patient to a high degree of suffering from the above-mentioned adverse effects. It is generally believed among dentists that the risk of adverse events outweighs the therapeutic benefit of anti-inflammatory drugs.

7. This risk-benefit analysis has led to the failure of at least two potential anti-inflammatory drugs in clinical trials.

8. For example, the use of flurbiprofen (trade name ANSAID®), a non-steroidal anti-inflammatory drug primarily used for the treatment of arthritis, has been studied for its efficacy in the treatment of periodontal disease. Flurbiprophen was employed in animal and human studies with systemic administration and subsequently topical administration. The study results revealed that flurbiprophen provided marked protection from tissue destruction and bone loss in bacterially induced periodontitis. However, constant administration of the drug was necessary to maintain the effect and removal of the drug resulted in a rebound of disease. The toxicity of long term administration of non-steroidal anti-inflammatory drugs is well known.

9. Being unable to develop a dosing regimen with minimal side effects, the program for the use of flurbiprophen for treatment of periodontitis was abandoned.

10. In another development program, early experiments with the drug ketorolac (TORADOL® and ACULAR®) for the treatment of periodontal disease were promising. However, Phase III clinical trials failed to show efficacy and the program was abandoned.

11. These examples show that others have tried to develop an anti-inflammatory drug for the treatment of periodontal disease but have failed. Consequently, to date there are no anti-inflammatory drugs in the market for the treatment of periodontal disease.

12. The use of cetylated fatty acids as anti-inflammatory formulations for the treatment of periodontal disease, in my opinion, is a major step forward. Cetylated fatty acids, to my knowledge, represent the first compounds available today that provide the requisite anti-inflammatory effect without any adverse side effects.

13. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or patent issuing therefrom.

Dated: 11/29/08

By: /TE Van Dyke/
Thomas E. Van Dyke, DDS, PhD